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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,191	06/22/2000	Graham Edmund Kelly	7579.001	8264

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 03/19/2003

#13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/602,191

Applicant(s)

KELLY, GRAHAM EDMUND

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,9 and 11-13 is/are rejected.
- 7) ☒ Claim(s) 2,5,7,8 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 12.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Objections/Rejections Set For the in Office Action dated November 5, 2002***

1. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.
2. Claims 1, 3, 4, 6, 9, and 11-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma, *Atherosclerosis*, (1979), vol. 33, pages 371-375 (Sharma) in view of McCoy et al. U.S. Patent 4,379,177 (McCoy).
3. Claims 2, 5, 7, 8, and 10 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Applicant's Response dated February 5, 2003***

4. In the Response filed February 5, 2003, applicant presented arguments directed to the rejection of claims 1, 3, 4, 6, 9, and 11-13 under 35 U.S.C. 103(a) and the objection to claims 2, 5, 7, 8, and 10. Claims 1-13 are pending. An action on the merits of claims 1-13 is contained herein below.
5. The rejection of claims 1, 3, 4, 6, 9, and 11-13 under 35 U.S.C § 103(a), is maintained for the reasons of record set forth in the Office Action dated November 5, 2002.

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6. The objection to claims 2, 5, 7, 8, and 10 is maintained for the reasons of record set forth in the Office Action dated November 5, 2002

***Response to Arguments***

7. Applicant's arguments filed February 5, 2003 have been fully considered but they are not persuasive.

Applicant argues: 1) Sharma does not suggest the use of a health supplement comprising two or more of the enumerated phyto-estrogens; 2) Sharma does not suggest methods for treating or reducing the predisposition to elevated blood cholesterol by administration of a therapeutically effective amount of a health supplement comprising two or more of the enumerated phyto-estrogens; 3) Sharma does not teach the use of a pharmaceutically acceptable carrier; and 4) McCoy does not remedy the deficiencies of Sharma. The examiner respectfully disagrees.

The examiner disagrees with applicant's characterization of Sharma. Sharma teaches the administration of isoflavone compositions comprising biochanin A, formononetin and pratensein obtained from commonly used legumes [soy] for lowering levels of serum cholesterol and triglycerides of rats (page 373, paragraphs 1-2). Biochanin A, formononetin and pratensein were suspended in 0.25% aqueous methylcellulose [pharmaceutically acceptable carrier] at a concentration of 5 mg/ml. Applicant's assertion that the isoflavones are administered individually is noted; however, Sharma explicitly teaches, "In an earlier study (to be published) the crude isoflavone extract isolated from bengalgram, which was shown to be mainly biochanin A

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and formononetin, was found to reduce serum total cholesterol and ester cholesterol in rats fed a hypercholesterolemic diet." Clearly Sharma teaches a composition comprising two or more of the enumerated phyto-estrogens as being useful for reducing serum total cholesterol.

The formulation of pharmaceutical composition taught by Sharma into a solid form is seen to be within the purview of the skilled artisan. McCoy is cited to show that the formulation of a pharmaceutical composition into a solid form was within the purview of one of ordinary skill in the art at the time of the invention.

In the absence of some proof of a secondary nature to obviate the rejection as set forth in the Office Action dated November 5, 2002, or of some specific limitations which would tip the scale of patentability in the favor of the instantly claimed invention, it would have been obvious to one of ordinary skill in this art at the time of the invention to administer a therapeutically effective amount of a health supplement comprising two or more of the enumerated phyto-estrogens to treat subjects with elevated levels of cholesterol. Compositions comprising biochanin A, formononetin and pratensein, individually and in combination, are well recognized in the art for the treatment of elevated levels of cholesterol, and to formulate said composition into a solid form to obtain the same result is indeed *prima facie* obvious.

### ***Conclusion***

8. Claims 1-13 are pending. Claims 1, 3, 4, 6, 9, and 11-13 are rejected. Claims 2, 5, 7, 8, and 10 are objected to. No claims are allowed.

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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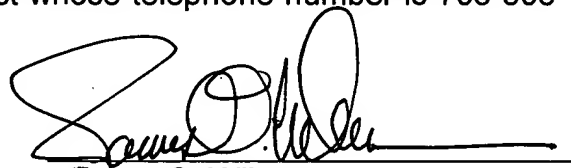
**Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD  
Examiner  
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James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

ptl  
March 13, 2003